

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 4

REMARKS

Claims 1-7 and 9-12 were pending in the subject application. By this Amendment, applicants have cancelled claims 3, 5 and 12 without disclaimer or prejudice, and amended claim 1. Support for the amendment to claim 1 may be found in the specification, *inter alia*, at page 5, lines 21-22 and at page 9, lines 1-2.

No issue of new matter is raised by this amendment. Upon entry of this Amendment, claims 1, 2, 4, 6, 7 and 9-11, as amended, will be pending and under examination in the subject application.

Rejection Under 35 U.S.C. § 112

The Examiner rejected claim 12 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, without conceding the correctness of the Examiner's position, applicants have canceled claim 12 without disclaimer or prejudice, thereby rendering this ground of rejection moot.

In view of the cancellation of claim 12, applicants request that the Examiner reconsider and withdraw his rejections on the basis of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. § 103

A. The Examiner has rejected claims 1, 2, 6, 7 and 9-11 under 35 U.S.C. §103(a) as allegedly unpatentable over Palpu (A*), Hong Yue (B*), Dehpour (U), Yoshida et al. (N), Lewis et al. (V) and Rao et al. (W).

Specifically, the Examiner asserted that each of the cited references teaches a composition for the treatment of ulcers comprising an ingredient recited in claim 1. The Examiner conceded that the references do not teach a composition comprising each of the instantly claimed ingredients as listed in claim 1, but alleged that each of the references does teach that each of the claim-designated powdered plant parts are useful for treating gastric ulcers.

The Examiner further asserted that one of ordinary skill in the art would have had a reasonable expectation of success in using the claimed ingredients to formulate the instantly claimed composition because at the time the invention was made, each of the powdered plant parts of *Asparagus racemosus* tuber, *Glycyrrhiza glabra* root, *Sesamum indicum* seed, unripe fruit of *Musa sapientum* and *Trachyspermum roxburghianum* was known in the art of herbal medicine to be useful for the treatment of gastric ulcers.

The Examiner further asserted that while the combined teachings of the references do not specifically teach combining the ingredients in the amounts claimed by the Applicant, the amount of a specific ingredient in a composition is a result effective parameter that a person of

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 6

ordinary skill in the art would routinely optimize. The Examiner further asserted that the references recognize that the amounts of the claimed ingredients can be modified and that it would have been customary for one of ordinary skill to determine the optimal amount of each of the ingredients to add in order to best achieve the desired results. The Examiner further asserted that absent some clear demonstration of unexpected results from the claimed composition, this optimization of ingredient amounts would have been obvious at the time the instantly claimed invention was made.

In response, applicants respectfully traverse the Examiner's rejection.

Claim 1 as now amended provides a herbal composition for the treatment of gastric ulcer, said composition comprising powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Aloe barbadensis* and *Evolvulus alsinoides*, a resin from *Ferula asafetida*, and one or more pharmaceutically acceptable additives or carriers, wherein said composition comprises each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportion has a value greater than zero.

Applicants first note that none of the prior art references teach the use of such ingredients together. Applicants further note that the combination of the ingredients in applicants'

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 7

composition provides unexpected results. Applicants maintain that the composition as now recited in claim 1 exhibits an unexpectedly high potency for treating gastric ulcers which is an unexpected result of combining the above-listed powdered plant ingredients. Applicants maintain that the composition of claim 1 exhibits synergistic properties as shown in Table 8, on page 18 of the application. Applicants also direct the Examiner's attention to Table 1 on page 12 which shows the increased protection of the composition of the invention compared with Omeprazole; and Table 3 on page 14 as well as page 14, lines 14-16 which establish that applicants' claimed composition has superior properties when compared with Omperazole. Applicants further direct the Examiner's attention to Table 5 on page 16, which demonstrates the superior protection afforded by the present composition. Finally, applicants direct the Examiner's attention to the Declaration of Dr. J. Madhusudana Rao, an inventor, attached hereto as Exhibit A. This Declaration shows that a composition containing equal proportions of the individual components by weight of the composition of claim 1 exhibit synergistic properties in the cold restraint stress induced ulcer (CRU) model in rats.

Accordingly, applicants maintain that the claimed composition provides unexpected results and is therefore unobvious over the combination of references cited by the Examiner. Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §103(a).

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 8

B. The Examiner has also rejected claims 1, 2, 6, 7 and 9-11 under 35 U.S.C. §103(a) as allegedly unpatentable over Palpu (A*), Hong Yue (B*), Dehpour (U), Yoshida et al. (N), Lewis et al. (V) and Rao et al. (W) in view of Purohit et al. (X), Yang (O), Khrenova et al. (U1), Warriar and McAnalley (C*).

Specifically, the Examiner has asserted that the combined teachings of Palpu, Hong Yue, Dehpour, Yoshida, Lewis and Rao teach the instantly claimed herbal composition for the treatment of gastric ulcer except for *Evolvulus alsinoides*, *Ferula asafetida*, *Coriandrum sativum*, *Cyclea Peltata* and *Aloe barbadensis* in equal proportions by weight. The Examiner further asserted that it would have been obvious to one of ordinary skill in the art to add the claim-designated ingredients to the composition taught by the combined teachings of Palpu, Hong-Yue, Dehpour, Yoshida, Lewis and Rao to provide the instantly claimed herbal composition because at the time the invention was made each of the ingredients were known in the art as being beneficial for making a composition to treat gastric ulcer as evidenced by the teachings of Purohit, Yang, Khrenova, Warriar and McAnalley. The Examiner asserted that each of Purohit, Yang, Khrenova, Warriar and McAnalley teaches a composition for the treatment of ulcers comprising an ingredient recited in claim 1.

The Examiner further asserted that it would have been obvious to one of ordinary skill in the art to formulate the claimed ingredients to make the claimed composition because it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 9

for the same purpose. The Examiner also asserted that the idea for combining them flows logically from their having been used individually in the prior art.

The Examiner further asserted that as each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

In response, applicants respectfully traverse the Examiner's rejection.

Claim 1 as now amended provides a herbal composition for the treatment of gastric ulcer, said composition comprising powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Aloe barbadensis* and *Evolvulus alsinoides*, a resin from *Ferula asafetida*, and one or more pharmaceutically acceptable additives or carriers, wherein said composition comprises each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportion has a value greater than zero.

Applicants again note that none of the prior art references teach the use of such ingredients together. Applicants further note that the combination of the ingredients in

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 10

applicants' composition provides unexpected results. Applicants maintain that the composition as now recited in claim 1 exhibits an unexpectedly high potency for treating gastric ulcers which is the unexpected result of combining the above-listed powdered plant ingredients in the amounts claimed. Applicants maintain that the composition of claim 1 exhibits synergistic properties as shown in Table 8, on page 18 of the application. Applicants also direct the Examiner's attention to Table 1 on page 12 which shows the increased protection of the composition of the invention compared with Omeprazole; and Table 3 on page 14 as well as page 14, lines 14-16 which establish that applicants' claimed composition has superior properties when compared with Omperazole. Applicants further direct the Examiner's attention to Table 5 on page 16, which demonstrates the superior protection afforded by the present composition. Applicants further direct the Examiner's attention to the Declaration of Dr. J. Madhusudana Rao, a coinventor, attached hereto as Exhibit A, which shows that a composition containing equal proportions of the individual components by weight of the composition of claim 1 exhibit synergistic properties.

Accordingly, applicants maintain that the claimed composition provides unexpected results and is therefore unobvious over the combination of references cited by the Examiner. Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §103(a).

Applicants: Janaswamy Madhusudana Rao, et al.
Serial No.: 10/695,471
Filed: October 28, 2003
Page 11

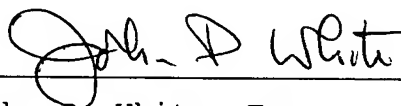
Summary

A sincere effort has been made to present claims which clearly distinguish over the cited combination of references. In view of the preceding amendments and remarks, the Examiner is urged to withdraw the rejection of the claims and to pass the application to allowance.

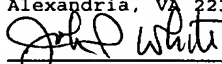
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$130.00 fee for an extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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January 26, 2009
John P. White Date
Reg. No. 28,678